

(1) Allocate adequate space to the PRO for its conduct of review at the times the PRO is conducting review.

(2) Provide patient care data and other pertinent data to the PRO at the time the PRO is collecting review information that is required for the PRO to make its determinations. The facility must photocopy and deliver to the PRO all required information within 30 days of a request. PROs pay hospitals paid under the prospective payment system for the costs of photocopying records requested by the PRO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the PRO. When the PRO does post-admission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to PRO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the PRO, that each case subject to preadmission review has been reviewed and approved by the PRO before admission to the hospital or a timely request has been made for PRO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the PRO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a PRO, makes a timely re-

quest for preadmission review and the PRO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the PRO.

(c) *Photocopying reimbursement methodology for prospective payment system hospitals.* Hospitals subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the hospitals' responsibility to the PROs to provide photocopies of requested hospital records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by CMS as follows:

(1) *Step one.* CMS adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB Circular A-76.

(2) *Step two.* CMS divides the amount determined in paragraph (c)(1) of this section by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.

(3) CMS adds to the per-page labor cost determined in paragraph (c)(2) of this section the per-page costs of supplies.

(d) *Appeals.* Reimbursement for the costs of photocopying and mailing records for PRO review is an additional payment to hospitals under the prospective system, as specified in § 412.115 of this chapter. Thus, appeals concerning these costs are subject to the review process specified in part 405, subpart R of this chapter.

[50 FR 15330, Apr. 17, 1985, as amended at 57 FR 47787, Oct. 20, 1992; 59 FR 45402, Sept. 1, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999]

#### **§ 476.80 Coordination with Medicare fiscal intermediaries and carriers.**

(a) *Procedures for agreements.* The Medicare fiscal intermediary or carrier

must have a written agreement with the PRO. The PRO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The PRO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, CMS will assist them in resolving matters in dispute.

(2) The PRO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from CMS, before it makes conclusive determinations for the Medicare program, unless CMS finds that the fiscal intermediary or carrier has—

(i) Refused to negotiate in good faith or in a timely manner; or

(ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) *Content of agreement.* The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

(i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and

(ii) Initial denial determinations and revisions of these determinations as a result of reconsideration, or reopening all approvals and denials with respect to cases subject to preadmission review, and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by CMS; and

(4) Any other matters that are necessary for the coordination of functions.

(c) *Action by CMS.* (1) Within the time specified in its contract, the PRO must submit to CMS for approval its agreement with the Medicare fiscal intermediaries and carriers, or if an agreement has not been established, the PRO's proposed administrative procedures, including any comments by the Medicare fiscal intermediaries and carriers.

(2) If CMS approves the agreement or the administrative procedures (after a finding by CMS as specified in paragraph (a)(2) of this section), the PRO may begin to make determinations under its contract with CMS.

(3) If CMS disapproves the agreement or procedures, it will—

(i) Notify the PRO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the PRO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) *Modification of agreements.* Agreements or procedures may be modified, with CMS's approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the PRO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) *Role of the fiscal intermediary.* (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the PRO, until it receives notice that the PRO has approved the admission after preadmission or retrospective review.

(2) A PRO's determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

**§ 476.82 Continuation of functions not assumed by PROs.**

Any of the duties and functions under Part B of Title XI of the Act for which a PRO has not assumed responsibility under its contract with CMS must be performed in the manner and to the extent otherwise provided for under the Act or in regulations.

PRO REVIEW FUNCTIONS

**§ 476.83 Initial denial determinations.**

A determination by a PRO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate